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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,295	08/23/2001	Stephen C. Knight	VEK-001.01	1054

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FOLEY HOAG, LLP
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EXAMINER

PORTER, RACHEL L

ART UNIT	PAPER NUMBER
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3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/938,295

Applicant(s)

KNIGHT, STEPHEN C.

Examiner

Rachel L. Porter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,9-12,17 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,9-12,17,19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 9/25/06. Claims 2-4,9-12,17 and 19-31 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-4,9-12, and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite because it recites "the match data comprises ***and/or*** location information..." The claim language should recite one or the other, but not "and/or." For the purpose of applying art, the Examiner will interpret this phrase as "or."

The preamble of claim 19 is vague and indefinite. In particular, it is unclear whether the Applicant intends to claim a system as a list of components/elements (a system comprising/consisting of/including: a server, a matcher...) or whether the applicant is claiming a method carried out by system components.

Claims 2-4,9-12, and 20-22 inherit the deficiencies of claim 19 through dependency, and are also rejected.

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4. Claim 22 recites the limitation " the instructions for storing the patient-specific data in a patient database " in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claims 3 and 19 do not recite a set of instructions.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Schmidt (US 6,839,678).

[claim 17] Schmidt discloses a method of recruiting a patient into a clinical trial, the method comprising:

- serving to the patient a questionnaire that includes at least one clinical trial eligibility question; (col. 4, lines 14-21)
- receiving from the patient patient-specific data that includes an answer to the at least one clinical trial eligibility question; (col. 4, lines 23-34)
- accessing criteria of one or more clinical trials; (col. 4, lines 36-41)

- determining whether the patient-specific data satisfies the criteria of one or more clinical trials; (col. 4, lines 36-48)
- inviting the patient to participate in a clinical trial for which the criteria have been determined to be satisfied, if any; (col. 4, lines 55-67)
- and if the patient chooses to participate, registering the patient in a database. (col. 4, lines 55-67; col. 5, lines 6-15)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-4, 9-12, and 19-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson et al (US 2002/0002474 A1) in view of Teagarden (US 6,014,631)

[claim 19] Michelson discloses a computer system for recruiting a patient into a clinical trial, the system configured as at least:

a server which: (par. 180)

- requests patient-specific data from the patient, the patient-specific data requested including clinical trial eligibility data; (par. 80-82)
- collects the patient-specific data from the patient; and (par. 82-83, 90)

- send match result data to the patient; (par. 167-168)

a matcher responsive to the patient's clinical trial eligibility data and to trial-specific criteria corresponding to the clinical trial to:

- determine whether a match exists between the patient and the clinical trial; (par. 83, and par. 166-167)

generate the match result data; and (167-168)

Michelson discusses the exchange of data in a secure environment among sponsors and investigators (par. 88). Michelson further discloses an Internet implemented system that uses a plurality of computers/databases, and but does not expressly disclose a system including a security layer.

Teagarden discloses a system including a security layer (Figures 9-11) which:

- prevents direct communication between the server and the other workstations ;
and receives the patient-specific data from the server;. (col. 14, lines 17-48)

The security layer disclosed by Teagarden separates network server (e.g. the Internet server) and from the workstations. Furthermore patient data and secure transactions pass through the security layer (e.g. prevent direct communication b/n the server and the matcher). (Figures 9-11; col. 14, lines 17-48) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Michelson with the teaching of Teagarden to include an added security layer. As suggested by Teagarden, one would have been motivated to include this feature to prevent unauthorized user access (col. 14, lines 29-32).

[claim 2] Michelson discloses system of claim 19, wherein the server communicates with the patient through a patient interface comprises an HTML-encoded web page.

(par. 80, 89-91 –Internet implementation, webpage, Figures 6A-N)

[claim 3] Michelson discloses the system of claim 19, further comprising a patient database in which patient-specific data is stored (par. 80-83; Figure 1B)

[claim 4] Michelson teaches the system of claim 19, further comprising a clinical trial database, in which the set of trial specific criteria is stored (par. 88, par. 162-170, Figure 1B)

[claim 9] Michelson discloses the system of claim 19, wherein the patient-specific data comprises answers to a questionnaire. (par. 80-83 ; Figures 1A; 15A-E)

[claim 10] Michelson discloses a system configured to send at least a portion of the patient-specific data to the clinical trial. (Figure 15E; par. 83)

[claim 11] Michelson teaches the system of claim 19, wherein the match result data comprises clinical trial contact or location information, and the server is configured to send match data to the patient. (Figure 14; par. 167-169)

[claim 12] Michelson discloses a system wherein the patient-specific data comprises at least one of disease of concern, demographic data, concomitant diseases, and medications. (Figures 15A-E)

[Claim 20] Michelson discloses the system of claim 19, wherein the system comprises at least two computers. (pars. 80-82)

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[claim 21] Michelson and Teagarden the system of claim 20 as explained in the rejection of claim 1, and 20. Furthermore, Teagarden discloses a system wherein the security layer runs on one of the computers, and the matcher runs on another computer. (Figures 9-11; col. 14, lines 17-48) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Michelson with the teaching of Teagarden for the reason provided in the rejection of claim 19.

[claim 22] Michelson discloses the system of claim 3, wherein further comprising instructions for storing the patient-specific data in a patient database wherein the instructions to store the patient-specific data in the patient database only after determining whether a match exists between the patient and the clinical trial. (par. 83, 168)

[claim 23] Michelson discloses a method of determining whether a patient is a candidate for a clinical trial, comprising:

- serving a questionnaire from a server to a patient through a patient interface;
(par. 80-83 ; Figures 1A; 15A-E)
- receiving at the server patient eligibility data submitted by the patient in response to the questionnaire; (par. 80,82-83, 89-91, Fig. 6A-N)
- sending the patient eligibility data from the server; (par. 80-83, 89-91, Fig. 1B)
- sending the patient eligibility data to a matcher; (par. 80-83, 89-91, Fig. 1B)

in the matcher:

- determining whether a match exists between the patient and the clinical trial by comparing the patient eligibility data to a set of trial criteria specific for the clinical trial; and (par. 166-167)
- returning match result information; (par. 167-168)
- sending to the server the match result information; and (par. 167-168)
- serving to the patient through the patient interface the match result information thus sent to the server. (par. 170)

Michelson discusses the exchange of data in a secure environment among system users. (par. 88). Michelson further discloses an Internet implemented system that uses a plurality of computers/databases, and but does not expressly disclose a system including a security layer.

Teagarden discloses a system including a security layer (Figures 9-11) which prevents direct communication between the server and the other workstations and receives the patient-specific data from the server (col. 14, lines 17-48).

The security layer disclosed by Teagarden separates network server (e.g. the Internet server) and from the workstations. Furthermore patient data and secure transactions pass through the security layer (e.g. prevent direct communication b/n the server and the matcher). (Figures 9-11; col. 14, lines 17-48) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Michelson with the teaching of Teagarden to include an added security layer. As suggested by Teagarden, one would have been motivated to include this feature to prevent unauthorized user access (col. 14, lines 29-32).

[claim 24] Michelson discloses a method, further comprising serving clinical trial contact or location information to the patient through the patient interface. (par. 169)

[claim 25] Michelson discloses a method further comprising serving a registration questionnaire to the patient through the patient interface after a match has been determined to exist between the patient and the clinical trial. (par. 168)

[claim 26] Michelson discloses a method further comprising receiving a set of registration information from the patient. (par. 168)

[claim 27] Michelson discloses a method further comprising adding the registration information to a patient database. (par. 168; Figure 24—subject database)

[claim 28] Michelson discloses a method further comprising sending at least part of the set of registration information to the clinical trial. (par. 169-170)

[claim 29] Michelson disclose a method further comprising comparing, in the matcher, the patient eligibility data to a second set of trial criteria and determining whether a match continues to exist between the patient and the clinical trial: (par. 169, 172)

[claim 30] Michelson and Teagarden the system of claim 23 as explained in the rejection of claim 23. Michelson discloses a system comprising at least two computers, (pars. 80-82), but does not specifically disclose a security layer. Teagarden discloses a system wherein the security layer runs on one of the computers, and the matcher runs on another computer. (Figures 9-11; col. 14, lines 17-48) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Michelson with the teaching of Teagarden for the reason provided in the rejection of claim 19.

[claim 31] Michelson discloses a method of determining whether a patient is a candidate for a clinical trial, comprising:

- serving a first questionnaire from a server to a patient through a patient interface; (par. 80-83 ; Figures 1A; 15A-E)
- receiving at the server a first set of patient eligibility data submitted by the patient in response to the first questionnaire; (par. 80,82-83, 89-91, Fig. 6A-N)
- sending the first set of patient eligibility data from the server; (par. 80-83, 89-91, Fig. 1B)
- sending the first set of patient eligibility data from the security layer to a matcher; (par. 80-83, 89-91, Fig. 1B)

in the matcher:

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- determining whether a match exists between the patient and the plurality of clinical trials by comparing the first set of patient eligibility data to a set of generic trial criteria generic to a plurality of clinical trials; and (par. 166-167)
- returning generic match result information; (par.166-167))
- if a match exists between the patient and the plurality of clinical trials:
 - o serving a second questionnaire from the server to the patient through the patient interface; (par. 168)
 - o receiving at the server a second set of patient eligibility data submitted by the patient in response to the second questionnaire; (par. 168-169)
 - o sending the second set of patient eligibility data from the server (par. 168-169)
 - o sending the second set of patient eligibility data ; (par. 168-169)

in the matcher:

- determining whether a match exists between the patient and the one clinical trial by comparing the second set of patient eligibility data to a set of specific trial criteria specific to one of the plurality of clinical trials; and (par. 169, 172)
- returning specific match result information; (par. 169-170)
- if a match exists between the patient and the one clinical trial:
 - o sending information about the one clinical trial ; and (par. 169-170)
 - o serving the clinical trial information to the patient through the patient interface. (par. 169-170)

Michelson discusses the exchange of data in a secure environment among system users. (par. 88). Michelson further discloses an Internet implemented system that uses a plurality of computers/databases, and but does not expressly disclose a system including a security layer.

Teagarden discloses a system including a security layer (Figures 9-11) which prevents direct communication between the server and the other workstations and receives the patient-specific data from the server (col. 14, lines 17-48). The security layer disclosed by Teagarden separates network server (e.g. the Internet server) and from the workstations. Furthermore patient data and secure transactions pass through the security layer (e.g. prevent direct communication b/n the server and the matcher). (Figures 9-11; col. 14, lines 17-48) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Michelson with the teaching of Teagarden to include an added security layer. As suggested by Teagarden, one would have been motivated to include this feature to prevent unauthorized user access (col. 14, lines 29-32).

Response to Arguments

9. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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